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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,464	06/22/2001	Gerard H. Llanos	CRD-0929	8413

27777 7590 05/20/2003

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EXAMINER
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FERKO, KATHRYN P

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/887,464

Applicant(s)

LLANOS ET AL.

Examiner

Kathryn Ferko

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 10-13, 15-17 and 52 is/are pending in the application.
- 4a) Of the above claim(s) 18-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-13, 15-17 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 18-51 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

This is a response to the amendment dated April 9, 2003. Claims 1-8, 10-13, 15-17 and 52 are pending. Claims 18-51 are subject to restriction.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-8, 10-11, 13, 15-17 and 52 are rejected under 35 U.S.C. 102(a and/or e) as being anticipated by Ding et al in US Patent No. 6,284,305.

Regarding claims 1-8, 10-11, 13, and 15-17, Ding et al. disclose a local drug delivery apparatus having a medical device for implantation into a treatment site of a living organism, as recited in column 1, lines 11-21 and column 3; at least one agent (such as that recited in column 7, lines 30-45) in therapeutic dosages incorporated in a polymeric matrix (as recited in column 4, lines 18-22) and affixed to the medical device for the treatment of reaction by the living organism caused by the medical device or implantation thereof, as recited in column 4, lines 10-67; a lubricious material (such as the matrix/undercoat 102,

103 containing the drug as well as the top coat 104) for preventing the at least one agent from separating from the medical device prior to implantation of the medical device at the treatment site, the lubricious material being affixed to the at least one of the medical device or a delivery system for the medical device, as recited in column 3, lines 24-58; a medical device the is an intraluminal medical device, as recited in column 3, lines 62-67; an intraluminal device that is a stent, as recited in column 3, lines 65-67; an at least one agent that is an anti-proliferative, as recited in column 7, line 34; an at least one agent that is an anti-inflammatory, as recited in column 7, line 35; an at least one agent that is an anti-coagulant, as recited in column 7, line 33; an at least one agent that is an immunosuppressant, as recited in column 7, lines 30-45 and column 14, line 54; an at least one agent that is a non-viral gene introducer, as recited in column 7, lines 30-45 where non-viral gene introducers fall within the categories; a lubricious coating that is incorporated onto the medical device, as recited in column 4; a lubricious coating that is a silicone-based material, as recited in column 7, lines 19-29; a water soluble powder that is incorporated onto the medical device, are recited in column 5, lines 1-11 and column 14, lines 1-20 where a powder is defined as "finely dispersed solid particles" in The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company; a water soluble powder that is an anti-oxidant, as recited in column 7, lines 19-29; and a water soluble powder that is an anti-coagulant, as recited in column 7, lines 19-29.

With regard to claim 52, Ding et al. disclose a local drug delivery apparatus having a medical device for implantation into a treatment site of a living organism, as recited in columns 3 and 4; at least one agent (such as that recited in column 7, lines 30-45) in therapeutic dosages releasably affixed to the medical device for the treatment of reactions by the living organism caused by the medical device or the implantation thereof, as recited in columns 3 and 4; and a water soluble powder for preventing the at least one agent from separating from the medical device prior to implantation of the medical device at the treatment site, the water soluble material being affixed to at least one of the medical device or a delivery system from the medical device, as recited in column 3, lines 24-59, column 5, lines 1-11 and column 7, lines 19-44.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. in US Patent No. 6,284,305.

Ding et al. disclose the invention with the exception of a lubricious coating that is incorporated onto the delivery system for the medical device. On the other hand, it would be obvious to one with ordinary skill in the art to assure that there is a coating on the delivery system for the purpose of lubrication to provide ease

Art Unit: 3743

of insertion and maintenance of the therapeutic drug on the stent. Commonly, stents are inserted with balloon catheters and it would be obvious to one with ordinary skill in the art to provide lubrication to assure proper insertion.

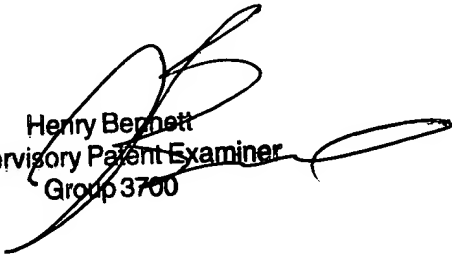
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Ferko whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KF  
May 14, 2003

  
Henry Bennett  
Supervisory Patent Examiner  
Group 3700